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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------|
| 09/900,144 | 07/09/2001 | Atsushi Maki | 500.34077CC3 | 6500 |
| 20457 | 7590 | 07/28/2005 | EXAMINER | |
| ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-3873 | | | MANTIS MERCADER, ELENI M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,144

Applicant(s)

MAKI ET AL.

Examiner

Eleni Mantis Mercader

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-46 is/are allowed.
- 6) ☒ Claim(s) 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Gopinath of record and as evidenced by Chance et al. (1993) and Kwan (2004).

Gopinath teaches on pages 44-45 a living body optical measurement system comprising a light irradiation means for irradiating light on the surface of a living body (tungsten lamps). The phrase “light irradiation means for irradiating light on the surface of a living body” invokes 35 USC 112, 6th paragraph. Page 41 of Applicant’s specification describes some examples (semiconductor laser, a titanium/sapphire laser or LED) of light sources. While they are not identical in structure to a tungsten lamp disclosed in Gopinath, the disclosed tungsten lamp provides prima facie case of equivalence.

MPEP 2183 states “if the examiner finds a prior art element (performs the function specified in the claim, (B) is not excluded by an explicit definition provided in the specification of an equivalent and (C) is an equivalent of the means- (or step-) plus function limitation, the examiner should provide an explanation and rational in the Office Action as to why this prior art element is an equivalent.” In this case, the tungsten light source does perform the same function of irradiating light on the surface of the living body and it is not excluded by the discussion on

page 41 of Applicant's disclosure. (Note the phrase "CAN be used as the light source."
(emphasis added)).

Also at least two factors in MPEP 2183 demonstrate an equivalent means-plus-function limitation that the tungsten lamp performs the identical function specified in the claim in substantially the same way and produces substantially the same results as the corresponding element in the specification. The Gopinath along with the articles of Kwan and Chance show that the RunMan dual wavelength NIRS unit is an optical probe, much like that disclosed on page 41 and Figure 15 of the Applicant's specification. (Kwan and Chance are used as extrinsic evidence to show the components of the RunMan unit). Furthermore, the tungsten light sources operate within the same wavelengths (760-850 nm) as that disclosed by Applicant (600-1400 nm). Thus, there are insubstantial differences between the prior art element and the claimed invention.

Gopinath also discloses a light detecting means for detecting the intensity of light (two silicon diode sensors-see Kwan and Chance articles) transmitting through the interior of the living body and going out of the surface of the living body (pages 44-45 of Gopinath describe detecting light intensity of unabsorbed reflected light). This phrase invokes 35 USC 112, 6th paragraph. The silicon diode sensor is an identical structure to the disclosed photodiode on page 42, line 15 of Applicant's specification.

Finally, Gopinath discloses that at least two sets of combination light irradiation and light detection positions are provided (pages 44-45 state measurements are taken on both sides of the head to detect a suspected hematoma), and a logarithmic difference signal between detection signals for the respective sets is used as a measured signal (page 45 showing the change in

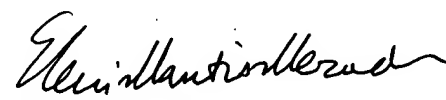
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optical density (OD) , which equates to the logarithmic difference between the light intensity on the normal and hematoma side of the head). See also page 44 of Applicants' specification showing a similar equation for its logarithmic difference signal.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737